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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,149	03/25/2004	Gary K. Michelson	101.0093-02000	7390

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EXAMINER	
SWIGER III, JAMES L	
ART UNIT	**PAPER NUMBER**
3733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,149	MICHELSON, GARY K.	
	Examiner	Art Unit	
	James L. Swiger	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/25/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4-13, 15, 17-19, 21-22, 25-26, 27-28, 29-30, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Cauthen (US Pub. 2003/0135220). Cauthen teaches a method of spinal implant insertion including the steps of positioning into a disc space a guard (par. 0043) that has a body (12), and an extension (20/35), that also has a first portion (18) and a second portion (37) and has an articulating hinge that allows the two extensions to move relative to one another, as they are associated with the body element (par. 0034). The method of Cauthen is capable of creating a vertebral disc space, defined as the 'open position,' since it rotatably articulates and

may allow for other devices to pass through, therefore creating a height in the space (par. 0012). The method of Cauthen also may be performed posterially or on both sides of the spinal midline (Figs. 5 and 7), and may be performed using multiple extensions (20/35). In rotatably articulating the guard, angulation may be induced to the vertebrae, and when this space is created, a driving extension may be introduced into the disc space (par. 0045, 46). This angulation of the vertebrae may be considered as inducing lordosis, as defined as a curvature of the spine, enhanced by the vertebrae moving appropriately away from one another in the spirit of the method of the invention. The body of the device may also be secured/locked (par. 0045, line 15), a device such as bone removal device may be inserted (par 0038) that may allow for reaming in the implantation space. The end plates of the vertebrae formed as a result of the preparation by a device may be considered 'opposed receiving surfaces' (see par. 0047). The method of Cauthen also discloses a step of inserting an implant (see Claim 17, item (d)) through the guard, and a step that is capable of having the implant inserted after the guard is removed from the disc space since sufficient clearance should still exist in the space. Also the implant inserted is capable of being significantly sized and shaped to correspond to the height of the space formed through the guard. Cauthen also discloses a step of inserting and removing an implant inserter (see claim 17, (a) and (f)), utilizing a hollow therebetween that may be used in conjunction with fusion-promoting substances (stated functionally), and wherein the implant is capable of being inserted into a space in the spine, and wherein it may be inert or a bone graft-type material depending on the material (see par. 0042). Depending on the material, it may

be artifical for use on the significantly-shaped implant to mirror the shape of the spinal disc. Also, Cauthen discloses a step where the upper and lower members maybe arcuate (the wedge 41 may be considered a partially arcuate implant) that works in conjunction with the spinal fusion implant. Further the extensions of the device may be collapsed for removal (Figs. 15 and 16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US 5,860,973). Cauthen discloses the claimed method except for a step including inserting of two implants, the two implants each having a width that is less than half the disc space, since it must fit into the same space as one implant. Michelson '973 discloses an implant where two may be used since it is appropriately sized and shaped that two of the implants may fit into a spinal implant space. (See Fig. 5) that allows for increased stability of the two vertebrae (Col. 2, lines 19-38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen the step of having two implants in a single vertebrae space in view of Michelson to better stabilize the two recovering vertebrae.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 in view of Young et al. (US 6,190,414). Cauthen discloses the claimed method except for a step including a spinal fusion implant has upper and lower surfaces with at least one opening adapted for permitting the growth of bone from adjacent vertebral bodies. Young et al. discloses an implant with apertures (166) that allow for bone growth between vertebral bodies (Col. 2, lines 33-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made incorporate into the method of Cauthen at least the step of including an implant allowing for bone growth between implants in view of Young et al. to better the fuse and stabilize the implants.

Claims 20, 23, 32-36, 40, 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 in view of Michelson (US 6,210,412). Cauthen discloses the claimed invention except for the step of threading or screwing the implant, using a fusion promotion substance when loading the implant, and wherein one of the substances may be hydroxyapatite. Michelson discloses an implant that is shaped to enable threading into the vertebral space (Fig. 1) that is designed to allow for increased anatomical lordosis and increased contact in surface area between the implant the vertebrae surface. (See Col. 7, lines 3-37).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 in view of Picha et al. (US 5,876,457). Cauthen discloses the claimed method except for an implant with surface projections configured to resist expulsion of the implant from the implant space. Picha discloses an implant with extending threads (12) that allow for the implant to be screwed in and draw the implant into the spine (Col. 3,

lines 12-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made incorporate into the method of Cauthen at least an implant with surface projections in view of Picha to better secure the implant.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 in view of Gruskin et al. (US Pub 2003/0023209). Cauthen discloses the claimed invention except for an implant that is incorporated with a material to prevent scarring. Gruskin et al. discloses a substance, namely a cross-linked polysaccharide having a positive charge that allows for the wound site to heal with less scarring. (See par. 0010). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen an anti-scarring additive in view of Gruskin et al. to better allow the wound area to heal with less damage.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '220 in view of Mansouri et al. (US Pub 2003/0229401). Cauthen discloses the claimed method of the spinal implant except for an implant having an antimicrobial agent. Mansouri et al. discloses an anti-microbe agent to prevent the colonization of bacteria on the surfaces of the implant or other parts of the device, or more specifically while treating a non-metallic medical device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of Cauthen an anti-microbal agent to prevent infection and a more successful surgical application. (par. 0010).

Response to Arguments

Applicant's arguments filed 11/20/2006 have been fully considered but they are not persuasive. With regards to the arguments regarding the perpendicular movement, it is still inherent in the performed method as rejected by Cauthen that the device move at least generally perpendicular to the spinal axis. At least a portion of Cauthen (22) articulates along an axis that is considered generally perpendicular to the axis formed along the longitudinal axis of the spine. Thus, the rejections listed *supra* remain.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2/20/07

JLS

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER